EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to Rhodiola rosea L. extract and reduction of mental fatigue pursuant to Article 13(5) of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
10.2903/j.efsa.2012.2805

Publication date:
2012

Document Version
Publisher's PDF, also known as Version of record

European Food Safety Authority

EFSA Journal 2012;10(7):2805

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to *Rhodiola rosea* L. extract and reduction of mental fatigue pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to *Rhodiola rosea* L. extract and reduction of mental fatigue. The food constituent that is the subject of the health claim is a dry powder extract of *Rhodiola rosea* L., which is standardised for its content of rosavins and salidroside. The Panel considers that *Rhodiola rosea* L. extract is sufficiently characterised. The claimed effect is "helps to stimulate intellectual functions in situation of stress after the first intake". Upon request by EFSA, the applicant clarified that the claimed effect related to the reduction of tiredness and fatigue in situation of stress. The target population proposed by the applicant is healthy adults in situations of fatigue and stress. The Panel considers that reduction of mental fatigue is a beneficial physiological effect. The applicant identified two published human intervention studies as pertinent to the health claim. These studies were carried out with a *Rhodiola rosea* L. extract which was standardised only for its salidroside content and not for its content of rosavins. The Panel notes that these studies were not undertaken with the food constituent, *Rhodiola rosea* L. extract, which is the subject of the health claim and which is standardised for both its rosavins and salidroside content. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the health claim. The Panel concludes that a cause and effect relationship has not been established between the consumption of *Rhodiola rosea* L. extract and reduction of mental fatigue.

KEY WORDS

Rhodiola rosea L., mental fatigue, health claims

[1] On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00336, adopted on 27 June 2012.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen for the preparatory work on this scientific opinion.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to *Rhodiola rosea* L. extract and reduction of mental fatigue pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(7):2805. [7 pp.]. doi:10.2903/j.efsa.2012.2805. Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to *Rhodiola rosea* L. extract and reduction of mental fatigue.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food constituent that is the subject of the health claim is a dry powder extract of *Rhodiola rosea* L., which is standardised for its content of rosavins and salidroside. The Panel considers that *Rhodiola rosea* L. extract is sufficiently characterised.

The claimed effect is "helps to stimulate intellectual functions in situation of stress after the first intake". Upon request by EFSA, the applicant clarified that the claimed effect related to the reduction of tiredness and fatigue in situations of stress. The target population proposed by the applicant is healthy adults in situations of fatigue and stress. The Panel considers that reduction of mental fatigue is a beneficial physiological effect.

The applicant identified two published human intervention studies as pertinent to the health claim. These studies were carried out with a *Rhodiola rosea* L. extract which was standardised only for its salidroside content and not for its content of rosavins. The Panel notes that these studies were not undertaken with the food constituent, *Rhodiola rosea* L. extract, which is the subject of the health claim and which is standardised for both its rosavins and salidroside content. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the health claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Rhodiola rosea* L. extract and reduction of mental fatigue.

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BACKGROUND

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 24/02/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 28/03/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- The applicant provided the missing information on 30/04/2012.
- The scientific evaluation procedure started on 04/05/2012.
- During its meeting on 27/06/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to *Rhodiola rosea* L. extract and reduction of mental fatigue.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: *Rhodiola rosea* L. extract and reduction of mental fatigue.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of *Rhodiola rosea* L. extract, a positive assessment of its safety, nor a decision on whether *Rhodiola rosea* L. extract is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Nutrilinks Sarl - Chemin de Beau-rivage 7 – Post code 96 CH-1000 Lausanne 21 - Switzerland.

Food/constituent as stated by the applicant

According to the applicant, 550-580 mg of a *Rhodiola rosea* extract contained in a food supplement.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect is "helps to reduce tiredness in case of stress".

According to the applicant, "*Rhodiola rosea* may help to stimulate intellectual functions in situation of stress. In fact, *Rhodiola rosea* is known as an adaptogen, i.e. a herbal preparation used to increase attention and endurance in fatigue and prevent/mitigate/reduce stress-induced impairments and disorders related to neuro-endocrine and immune system".

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "helps to reduce tiredness in case of stress". Alternative wordings proposed by the applicant: "results after the first intake", "helps to stimulate attention and memory in situation of stress after the first intake", "helps to manage/control/ to cope with stress after the first intake", "helps to manage/control/ to cope with stress".

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is healthy adults in situations of fatigue and stress.

The applicant has proposed an intake of three tablets per day providing 550 to 580 mg/day of *Rhodiola rosea* extract.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is a dry powder extract of *Rhodiola rosea* L.

Rhodiola rosea L. is a perennial plant of the Rhodiola genus in the Crassulaceae family. The dry powder extract of *Rhodiola rosea* L. is obtained by maceration of the roots of *Rhodiola rosea* L. with a water/ethanol (50-50 V/V) extracting solvent, and a subsequent filtration and spray-drying process on an inert support (potato maltodextrin). The dry powder extract of *Rhodiola rosea* L. is standardised to contain at least 3 % of rosavins (rosarin, rosavin, rosin) and at least 1 % of salidroside (rhodioloside). These constituents can be analysed in foods by established methods.

Information pertaining to the manufacturing process, control specifications, batch-to-batch variability and stability data has been provided by the applicant.

The dry powder extract of *Rhodiola rosea* L. is proposed to be used in tablets which contain 192 mg of *Rhodiola rosea* L. extract.

The Panel considers that the food constituent, *Rhodiola rosea* L. extract, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

Initially the claimed effect as proposed by the applicant was "helps to stimulate intellectual functions in situation of stress after the first intake".

Upon request by EFSA to define more clearly the claimed effect, the applicant indicated that the claimed effect related to the reduction of tiredness and fatigue in situations of stress.

The target population proposed by the applicant is healthy adults in situations of fatigue and stress.

The Panel considers that reduction of mental fatigue is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Science Direct, PubMed/Medline, Scirus, Mary Ann Liebert, SpringerLink, Wiley Interscience, and Google Scholar using search terms alone or in combination ("cognitive function" OR "intellectual function" OR "mental work" OR "mental performance" OR "cognitive work" OR "cognitive performance") AND "rhodiola" AND "stress". The inclusion criteria were studies performed with ingested extract of *Rhodiola rosea* L. titrated for salidroside (or rhodioloside), carried out with people under stress and using cognitive tests immediately after the first intake, and after a maximum of one month of supplementation. Review articles were excluded. Two studies were excluded by the applicant as they were carried out with low doses of *Rhodiola rosea* L. extract.

The applicant identified two published human intervention studies (Shevtsov et al., 2003; Olsson et al., 2009) as pertinent to the health claim. These studies were carried out with *Rhodiola rosea* L. extract SHR-5 which was titrated only for its salidroside content and not for its rosavin content. During the validation process, EFSA invited the applicant to clarify how the *Rhodiola* extract SHR-5 used in these studies related to the extract of *Rhodiola rosea* L. which is the subject of the health claim, and which is standardised for both its rosavins and salidroside content. The applicant acknowledged that no information on the rosavin content of *Rhodiola rosea* L. extract SHR-5 was available.

The Panel notes that the studies by Shevtsov et al. (2003) and Olsson et al. (2009) were not undertaken with the food constituent, *Rhodiola rosea* L. extract, which is the subject of the health claim. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the health claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Rhodiola rosea* L. extract and reduction of mental fatigue.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, *Rhodiola rosea* L. extract, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is "helps to stimulate intellectual functions in situation of stress after the first intake". The target population as proposed by the applicant is healthy adults in situations of fatigue and stress. Reduction of mental fatigue is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of *Rhodiola rosea* L. extract and reduction of mental fatigue.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on *Rhodiola rosea* L. extract and reduction of mental fatigue pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0331_BE). February 2012. Submitted by Nutrilinks Sarl.

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Shevtsov VA, Zholus BI, Shervarly VI, Vol'skij VB, Korovin YP, Khristich MP, Roslyakova NA and Wikman G, 2003. A randomized trial of two different doses of a SHR-5 Rhodiola rosea extract versus placebo and control of capacity for mental work. Phytomedicine, 10, 95-105.